THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER; TEAMSTERS HEALTH SERVICES AND INSURANCE PLAN LOCAL 404; and UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND on behalf of themselves and all others similarly situated, Plaintiffs, v. ABBOTT LABORATORIES; and ABBVIE Inc., Defendants.	Case No. 13-cv-5865 JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

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NATURE OF THE CASE

I. INTRODUCTION

1. This class action is brought by Plaintiffs Sidney Hillman Health Center of Rochester, Teamsters Health Services and Insurance Plan Local 404, and United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund (collectively "Plaintiffs"), health benefit providers, individually and on behalf of classes of similarly situated entities (the "Class" and three individual state "Subclasses," as defined below), to recoup not less than hundreds of millions of dollars they paid to Defendant Abbott Laboratories ("Abbott," or the "Company") as a result of Abbott's scheme to increase sales of the drug Depakote by illegally marketing it for uses for which it was neither approved nor shown to be efficacious.

2. Since its initial approval by the Food and Drug Administration ("FDA") in 1983, Abbott has marketed and sold Depakote (divalproex sodium) in various forms. The FDA has approved the various forms of Depakote for three limited indications.

3. Depakote is an anticonvulsant (anti-seizure drug): it is indicated as monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizures. Depakote was approved in 1995 for the treatment of acute mania or mixed episodes associated with bipolar disorder. Depakote has not been approved, however, for the long-term treatment of mania and controlled clinical trials have failed to demonstrate its effectiveness for such use. Depakote was approved in 1996 for the prophylaxis (prevention) of migraine headaches. It is not, however, indicated for the treatment of migraine headaches, nor is there evidence that Depakote is effective in the treatment of acute migraine headaches.

4. Rather than market Depakote for its limited indications, Abbott, embarked on a scheme to market the drug for a variety of uses for which it had never sought or obtained FDA

approval, including treatment of schizophrenia, control of agitation/aggression in elderly dementia patients, bipolar depression (in adults and children), developmental delay in children, and symptoms of narcotic drug withdrawal. Abbott had no reliable evidence of the drug's safety or efficacy for the treatment of those conditions. Moreover, Abbott knew or should have known that its misbranding of Depakote could jeopardize patients' safety.

5. Abbott's promotion of Depakote for off-label purposes, alone and in combination with misrepresentations or intentional omissions of material information with regard to the drugs' safety and efficacy, violated, among other things, the Food, Drug and Cosmetics Act. 21 U.S.C. §§ 301, *et seq*.

6. When the FDA approves a drug, it also approves labeling which lists the drug's "indications," that is, the conditions under which the product is to be used. Although physicians need not limit their prescriptions to the FDA approved indications, pharmaceutical manufacturers generally are prohibited from promoting their products for other than the indicated uses (sometimes referred to as "off-label" uses).

7. With the help of intermediary marketing firms and shadow entities funded by Abbott, as well as physicians paid to influence other doctors in exchange for lucrative kickbacks, Abbott aggressively marketed and sold Depakote for off-label uses.

8. From 1998 through 2012 (the "Class Period"), Abbott implemented these marketing schemes, dramatically increasing Depakote sales and paving the way for Abbott to profit at the expense of Plaintiffs and other Class members. By 2005, Abbott's sales of Depakote hit the billion dollar mark. In 2007, Depakote sales reached $1.5 billion.

9. Abbott controlled and conducted one or more enterprises through which it promoted Depakote's off-label use and made misrepresentations regarding the safety and

efficacy of the drug for unapproved uses. In addition, Abbott paid, or with the assistance of intermediaries, caused to be paid, kickbacks to promote both on-label and off-label sales.

10. On May 7, 2012, Abbott was held accountable for years of wrongful conduct when it pled guilty to a violation of the Food, Drug and Cosmetics Act and agreed to pay $1.6 billion to federal and state governments to address criminal sanctions and sanctions under relevant False Claims Acts. Unfortunately, these sanctions were insufficient to compensate for the harm caused to the Class and Subclasses.

11. Indeed, Abbott probably calculated both its risk of being caught and its potential civil and criminal exposure assuming its only liability would be to the Medicare, Medicaid, and Tricare systems. But Abbott's illegal conduct also created significant liability to private payors of Depakote under Federal law (the Racketeer Influenced and Corrupt Organizations Act 18 U.S.C. § 1962), state deceptive trade practice acts, and the common law.

II. PARTIES

Plaintiffs

12. Sidney Hillman Health Center of Rochester ("Hillman") is a multi-employer employee welfare benefit plan headquartered in Rochester, New York that provides medical benefits to employees and retirees (and their spouses/dependents) who are members of a Local affiliated with the Rochester Regional Joint Board of Workers United. Hillman Center currently serves thousands of beneficiaries, mainly located in the State of New York. Throughout the Class Period, Hillman Center has paid or reimbursed eligible beneficiaries' prescription drug benefits for off-label use of Depakote and was injured by the conduct alleged herein.

13. Teamsters Health Services and Insurance Plan Local 404 ("Local 404") is a health services fund headquartered in Springfield, Massachusetts. Local 404 serves more than 1,000

beneficiaries. During the Class Period, Local 404 paid tens of thousands of dollars for its beneficiaries' Depakote prescriptions, and was injured by the conduct alleged herein.

14. United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") is a multi-employer employee welfare benefit plan headquartered in Park Ridge, Illinois. The UFCW provides benefits to thousands of employees of retail food stores, meat markets, nursing homes, and similar industries (and the employees' families), who are members of the United Food and Commercial Workers Union in the Midwest region. Throughout the Class Period, UFCW has paid or reimbursed eligible beneficiaries' prescription drug benefits for off-label use of Depakote and was injured by the conduct alleged herein.

Defendants

15. Abbott is an Illinois corporation. Abbott is headquartered and maintains its principal place of business in Abbott Park, Illinois. Prior to 2013, Abbott engaged in the global business of development, manufacturing, marketing and sale of prescription drugs and related products**.** At the end of 2012, Abbott separated into two companies, one focused on the development and sale of medical products (Abbott), and the other focused on the development and sale of research-based pharmaceuticals (AbbVie, Inc.).

16. AbbVie, Inc. ("AbbVie" referred to collectively with Defendant Abbott as the "Defendants") was incorporated in Delaware on April 10, 2012. It is headquartered and maintains its principal place of business in North Chicago, Illinois. AbbVie became an independent entity on January 1, 2013. Depakote, while originally developed, marketed, and sold by Abbott, is now marketed and sold in the United States by AbbVie. Abbott still continues to market Depakote outside of the United States.

III. OTHER PARTICIPANTS IN OFF-LABEL PROMOTION ENTERPRISES

The CENE Enterprise

17. The Council for Excellence in Neuroscience Education ("CENE") purported to be an organization of "nationally known clinicians in neurosciences, formed to develop a comprehensive, interactive and multi-dimensional continuing education program . . . in the rapidly growing field of neuroscience."

18. In truth, CENE was created by Abbott to facilitate off-label marketing of Depakote. From at least 2002 to 2008, CENE offered numerous interactive web conferences ("webinars"), dinner meetings, slide shows, and monographs to doctors in order to promote the off-label use of Depakote.

19. CENE also advertised itself to doctors as a way to earn up to 36-48 hours of free Continuing Medical Education ("CME") credits by completing activities on the CENE website. Off-label CME materials were available through CENE.com on an ongoing basis.

20. During the Class Period, CENE.com listed "faculty members" and "council members." Although not disclosed on CENE.com, nearly every "faculty member" and "council member" was either a member of Abbott's Speaker Bureau or received some form of financial compensation from Abbott.

21. ACCESS Medical Group ("ACCESS") is a limited liability company located at 1 North Franklin Street, Chicago, Illinois 60606. ACCESS purports to be a communications company specializing in supporting "pharmaceutical, biotechnology, and medical device companies." ACCESS represents that it provides "advocacy development and local program execution." ACCESS' website states that the company uses its "scientific training, writing expertise, and business acumen" to educate pharmaceutical companies' target audiences and strategically enhance their brand value. Abbott hired ACCESS to create and/or enhance

CENE.com. It was ACCESS that created slide show presentations, used by doctors working with Abbott's speakers bureau, for the purposes of marketing Depakote off-label and without accurate representations concerning its safety and efficacy. Abbott is still listed as a client on ACCESS' website.

22. Together, Abbott, CENE, the CENE "faculty members," CENE "council members," and ACCESS make up the "CENE Enterprise."

The PharmaCare Enterprise

23. PharmaCare Strategies, Inc. ("PharmaCare Strategies"), located in Santa Rosa, Florida, is a purported "market development firm" specializing in assisting pharmaceutical manufacturers and pharmacy providers to position key products in specialty channels including managed care and hospital markets.

24. Abbott paid PharmaCare Strategies to train its employees at off-site locations to successfully promote illegal off-label uses for Depakote.

25. The "PharmaCare Enterprise" is comprised of Abbott, PharmaCare Strategies, and the Abbott sales representatives who carried out at a grassroots level the proscribed marketing activities alleged herein.

ABcomm Enterprise

26. ABcomm, Inc. ("ABcomm") is an Illinois corporation with its headquarters in Champaign, Illinois. ABcomm holds itself out as a provider of training activities for health professionals. ABcomm offers live activities including: national, regional and satellite symposia; specialty workshops; forums; and local activities including dinner activities and sponsorship of grand rounds. Grand rounds are monthly (sometimes more frequent) meetings of hospital and/or university physicians where important new medical developments are presented

and discussed. Often doctors receive CME credits for attending grand rounds. ABcomm also creates CME materials including: slide monographs; newsletters; and custom designed activities including CME calendars. ABcomm's President is Linda Baer, a former Medical Education manager at Abbott.

27. Abbott used ABcomm as a conduit to funnel money to physicians to drive prescription writing habits and increase illegal off-label Depakote sales.

28. Together, Abbott, ABcomm, and the physicians and other medical professionals to whom Abbott paid kickbacks, make up the "ABcomm Enterprise."

29. Controlled by Abbott, the CENE Enterprise, PharmaCare Enterprise, and ABcomm Enterprise illegally facilitated an increase in the amount of off-label Depakote prescriptions purchased by Plaintiffs and other Class and Subclass members.

IV. JURISDICTION AND VENUE

30. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, and 28 U.S.C. § 1964(c), because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

31. This Court has supplemental jurisdiction over the alleged state statutory and common law violations pursuant to 28 U.S.C. § 1367.

32. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), and 18 U.S.C. § 1965 because, among other reasons, both Abbott and AbbVie maintain their principal place of business in the state of Illinois.

V. FACTUAL ALLEGATIONS

A. DEPAKOTE

1. Depakote's FDA-Approved Uses and Restrictions

33. Divalproex sodium delayed release tablets, marketed by Abbott under the brand name "Depakote DR," were first approved by the FDA in 1983 for treating certain types of epileptic seizures. The drug was approved to treat "simple and complex absence seizures in adults" and complex partial seizures in adults and children age 10 and over.

34. In 1989, Abbott received FDA approval for Depakote Sprinkle Capsules ("Depakote Sprinkles"), as monotherapy for the treatment of simple and complex absence seizures, and adjunctively in patients with multiple seizure types including absence seizures. Depakote Sprinkles has not received approval for additional indications.

35. In May 1995, the FDA approved Depakote DR for treatment of acute manic episodes associated with bipolar disorder ("bipolar mania"). A manic episode is a distinct period of abnormally and persistent elevated, expansive, or irritable mood. Typical symptoms of mania include pressured speech, motor hyperactivity, reduced need for sleep, flight of ideas, grandiosity, poor judgment, aggressiveness, and possible hostility. The FDA has not approved Depakote DR for the continuing treatment of bipolar disorder or depression associated with bipolar disorder.

36. In 1996, the FDA further expanded the approved indications of Depakote DR to include prevention of migraine headaches in adults.

37. In 2000, Abbott introduced an extended-release tablet form of Depakote, called Depakote ER. It was approved by the FDA on September 4, 2000 "for prophylaxis of migraine headaches in adults."

38. On December 12, 2002, the FDA approved an additional indication of Depakote ER Tablets as monotherapy and adjunctive therapy in complex partial seizures in adults and in simple and complex absence seizures in adults. The FDA extended this indication on September 15, 2003, to include pediatric patients over age 10 for these types of seizures only.

39. In December 2005, Depakote ER was approved for treating acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features. In doing so, the FDA did not approve Depakote for the general treatment of bipolar disorder, depression associated with bipolar disorder, or as a maintenance therapy for bipolar disorder.

40. Depakote ER and Depakote DR have never been approved for use by children under the age of ten (for any use), nor have they been approved for patients under age of eighteen for uses other than as a treatment for the particular epileptic seizures listed above.

41. Depakote ER, Depakote DR, and Depakote Sprinkle Capsules (together "Depakote") were never approved by the FDA for use in treatment of Alzheimer's disease, other types of dementia, agitation associated with dementia, sundowning, insomnia, post-stroke seizure, ADHD, schizophrenia, mood disorder, other types of epilepsy beyond those listed in the label, or narcotic drug withdrawal.

2. Safety Issues: Depakote's Black Box Warnings

42. Although the FDA has determined that the benefits outweigh the risks of Depakote for its ***approved*** indications, Depakote is not a benign drug.

43. A warning for all patients taking valproate products (which includes Depakote) has been required in product labeling since 1981. In July 2000, the FDA issued a more stringent "black box warning" (the most urgent warning it can issue short of recall) regarding Depakote's

safety. The FDA required Abbott to change its product labeling and to send letters to health care providers that warned of a life-threatening side effect. The black box warning states in part:

> Cases of life-threatening pancreatitis have been reported in both children and adults receiving valproate. Some of the cases have been described as hemorrhagic with rapid progression from initial symptoms to death. Cases have been reported shortly after initial use as well as after several years of use. Patients and guardians should be warned that abdominal pain, nausea, vomiting, and/or anorexia can be symptoms of pancreatitis requiring prompt medical evaluation. If pancreatitis is diagnosed, valproate should ordinarily be discontinued. Alternate treatment for the underlying medical condition should be initiated as clinically indicated.

44. In addition, Depakote is classified by the FDA as a pregnancy "Category D" drug, a known teratogen. This means it should be used by pregnant women only if the patient would be placed at life threatening risk without it. The most serious birth defects associated with Depakote include spina bifida, intrauterine growth retardation, skeletal defects, cleft palate, neural tube malformations, and fetal death.

45. In 2007, a safety-related package insert was required warning women of the dangers of birth defects while pregnant and taking this medication. The patient information leaflet states in part:

> Before using any of these medications, women who can become pregnant should consider the fact that these medications have been associated with birth defects, in particular, with Spina Bifida and other defects related to failure of the-spinal canal to close normally. Approximately 1 to 2% of children born to women with epilepsy taking Depakote in the first 12 weeks of pregnancy had these defects (based on data from the Centers for Disease Control). The incidence in the general population is 0.1 to 0.2%. These medications have also been associated with other birth defects such as defects of the heart, the bones and other parts of the body. Information suggests that birth defects may be more likely to occur with these medications than some other drugs that treat your medical condition.

46. The FDA's black box warnings on the use of Depakote remain in effect today.

3. Depakote's Other Warnings, Precautions, and Serious Side Effects

47. Depakote also has a package insert warning for "somnolence in the elderly." In a multi-center trial described in Depakote's package insert, a significantly higher proportion of patients on Depakote had somnolence compared to those taking a placebo. This problem was so serious Abbott had to stop the study early.

48. Depakote's sedative effect, heightened when the dosage levels are increased, poses a particular hazard to a geriatric population susceptible to serious life threatening injury associated with falls. Seniors are more likely to fall than younger people because of slower reflexes, arthritis, reduced vision, balance deficits, and other problems associated with aging. Also, falls have more serious consequences in this population. Abbott specifically knew about the risk of falls in the geriatric population. Melissa Moore, an Abbott Long Term Care Specialist, prepared a PowerPoint training presentation explaining that falls are the second leading cause of death in the United States and "75% occur in older adults." This PowerPoint presentation noted that the Centers for Disease Control estimated that the cost of injuries related to falls would reach $32.4 billion by year 2020, and $240 billion for hip fractures by year 2040. While the PowerPoint presentation cited the side effects of prescription drugs as a factor in causing falls, the presentation only mentioned anti-psychotics and not Depakote.

49. Depakote also poses certain risks to teenage girls. Specifically, some studies indicate that Depakote causes polycystic ovary syndrome ("PCOS"), the symptoms of which are obesity, irregular menstruation, acne, and excessive amounts or effects of androgenic (*i.e.*, masculine) hormones.

B. ILLEGAL MARKETING SCHEMES PERTAINING TO THE OFF-LABEL USE OF DEPAKOTE FOR BEHAVIOR DISORDERS RELATED TO DEMENTIA AND/OR ALZHEIMER'S DISEASE

1. Regulation of Abbott's Marketing Practices and Restrictions on Promotion of "Off-Label" Uses for Prescription Drugs

50. The FDA closely regulates the marketing and promotion of prescription drugs. Under the Food Drug and Cosmetic Act, and the regulations promulgated thereunder, all information provided by a drug company about its products, whether on or off-label, whether directed at consumers or physicians, must be fair and balanced.

51. To be fair and balanced, information about a drug company's products must accurately and fairly present all data relevant to any information provided. Practically speaking, a pharmaceutical company must present positive as well as negative information it knows about its products. Drug companies are prohibited from presenting half-truths or selectively disclosing only favorable information. In other words, pharmaceutical companies must make full disclosures. *See* 21 C.F.R. § 202.1 (e)(4)(5)(6)(7).

52. Abbott was aware of these FDA regulations and routinely trained its marketing personnel that they had to present all negative information along with any positive information. But this training was merely window dressing, concealing Abbott's actual practices.

53. Abbott's promotion of its products for off-label uses was also closely regulated. Generally, drug companies can only promote their products for FDA-approved uses. Sales personnel cannot initiate discussions of off-label uses with physicians during sales visits, and off-label uses are not supposed to be discussed in any promotional event sponsored by a drug company.

54. In limited circumstances, and following FDA guidelines, drug companies can provide information concerning off-label uses.

55. For example, the regulations allow drug companies to provide an unrestricted grant to an accredited independent sponsor of continuing medical education programs, provided the drug company does not influence the content of the program. This means that a drug company cannot select the topics to be presented at such programs or approve the speakers or the content to be provided. Only programs that are truly independent of the drug companies are supposed to qualify for this exception. *See* 42 U.S.C. 1320a-7b(b); *See also* Office of the Inspector General, Compliance Program Guidance for Pharmaceutical Manufactures at 20 (April 2003)("Pharmaceutical manufacturers sometimes provide grant funding for a wide range of educational activities").[1] While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchasers, GPOs, PBMs and similar entities raise concerns under the anti-kickback statute. Funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate. Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes.

56. The regulations also allow drug companies to provide off-label information to *bona fide* medical consultants, provided the actual purpose of the consultation is to have the persons retained provide consulting services to the drug company.

57. The regulations also allow drug companies to communicate off-label information to physicians in response to a *bona fide*, unsolicited request from a physician, but only information specifically responsive to the physician's request.

58. And, like all other information a drug company disseminates, off-label information, written or otherwise, is required to be "fair and balanced."

[1] http://oig.hhs.gov/fraud/docs/complianceguidance/ 042803pharmacymfgnonfr.pdf

2. In 1998, Abbott Created An Entire Sales Division To Off-Label Market Depakote

59. Abbott knew that the market potential for Depakote for its approved uses was modest. Until approximately 2004, Abbott used four divisions to market Depakote: the LTC division (primarily targeting "agitation associated with dementia," an unapproved use), the Neuroscience Sales division (targeting epilepsy), the SR Sales division (targeting psychiatric illnesses, many unapproved by the FDA), and the Institutional Sales division (serving universities, community mental health centers, and hospitals for a variety of diagnoses). In 2004, Depakote was also promoted through a consolidated division titled "Specialty Accounts."

60. Abbott encouraged off-label marketing of Depakote through compensation packages that either directly or indirectly rewarded sales representatives for the success of their off-label marketing activities.

61. In defining its market, Abbott instructed its sales representatives that Depakote's competitors were an array of psychopharmacological drugs, including but not limited to, antipsychotics (Risperdal, Seroquel, Geodon, and Abilify) and anticonvulsants (Trileptal and Lamictal). These drugs had indications that were different than Depakote. Abbott provided sales representatives with detailed data showing use of these drugs by particular physician(s) and institution(s).

62. Further, Abbott challenged its sales representatives to "convert" physicians or institutions prescribing these drugs to instead prescribe Depakote to patients suffering from agitation associated with dementia or else to encourage physicians to add a Depakote prescription. Abbott encouraged the conversion from Risperdal, Seroquel, Geodon, Trileptal, Lamictal, and Abilify to Depakote or the addition of Depakote to these drugs even though these drugs' indications and side effects are different from Depakote. By encouraging the conversion

of other drugs, with different indications, to Depakote, Abbott engaged in an additional form of off-label marketing.

63. Abbott's definition of the market and its encouragement to its sales representatives to have patients switch from other drugs or to add Depakote to an existing regimen put patients in danger. The competitor drugs did not have the same indications, side effects, or dosing requirements. In particular, the use of Depakote with atypical antipsychotic medications has never been approved to treat agitation associated with dementia.

64. Abbott used a system, called "Working The Wheel" or "account wheel," to target Depakote off-label marketing to physicians and institutions which Abbott believed would potentially yield the most off-label prescriptions of Depakote for agitation associated with dementia. In this "Wheel" system, Abbott directed its sales representatives to the "right customers," specifically those able to increase off-label use.

65. In or about January 2004, in furtherance of targeting the "right customers" to increase off-label sales, Abbott began purchasing prescription data from Health Market Science, Inc., which tracked prescription volume and diagnoses data by medical institution or institutional pharmacy.

66. Abbott sales representatives accessed this prescription data on-line in a spreadsheet format called the Functional Institutional Market Report ("Functional IMR"). The Functional IMR, which was regularly updated and provided to Abbott sales representatives, showed among other things:

a. the quantity of prescriptions written by physicians at particular medical institutions and/or provided by long-term care pharmacy providers for Depakote, Risperdal, Seroquel, Zyprexa, and other psychoactive drugs;

b. the diagnoses codes for which these drugs were prescribed; and

c. the relative national ranking of each medical institution or long-term care pharmacy based on the volume of Depakote prescriptions written.

67. Abbott developed a "metric" for evaluating physician prescription data for each physician tracked. Abbott was able to manage the influence it exerted over doctors the Company enlisted to participate by sorting each physician into a particular category, which provided the means for Abbott sales representatives to target physicians, determine "call frequency and messaging" for individual physicians, and "establish share goals" for individual physicians (*i.e.*, Depakote sales goals for physicians). These physician categories were: "loyalist," "grower," "bleeder," "potential," "maintain," or "low/no." Abbott defined the first four of these categories as follows:

- "Loyalist" physicians frequently prescribed Depakote rather than other psychoactive drugs, including antipsychotics, for off-label uses promoted by Abbott in the long term care market.
- "Grower" physicians were those Abbott believed would continue to increase prescribing off-label Depakote prescriptions in the long term care market.
- "Bleeder" physicians formerly prescribed Depakote for off-label uses regularly in the long term care market, but were, at that time, prescribing other drugs with more frequency.
- "Potential" physicians were those Abbott believed could be converted to using Depakote, over other comparable drugs, in the long term care market.

68. The data pertaining to the number of prescriptions written by each physician for other drugs in other classes, including atypical antipsychotics, was used by Abbott to incentivize its Depakote sales representatives to "convert" physicians using other drugs for agitation associated with dementia.

69. For example, even though Risperdal is an antipsychotic and Depakote is an antiepileptic, Abbott provided financial incentives to its Depakote sales representatives to convince physicians to switch their patients to Depakote from Risperdal. Even though, like Depakote, the atypical antipsychotics do not have an indication for agitation associated with dementia, Abbott considered them to be "competitors" from which to capture business. By defining these drugs -- which were not the same as Depakote and were themselves marketed off-label -- as competitors, Abbott was furthering its unlawful marketing conduct.

70. In a concerted plan to conceal its wrongful conduct, Abbott forbade its sales representatives from putting their "call notes" (*i.e.*, brief summaries of discussions with doctors on sales calls, used by managers to track Abbott's sales representatives' progress) into the Company-wide computer system used by all Abbott Sales Representatives called "MAX."

71. Instead, Abbott instructed its sales representatives to record in MAX only the office visits with doctors, but to keep separate handwritten notes detailing the subject matter of the calls on paper, which were later faxed to their managers. Abbott's MAX system required its sales representatives to document the diagnosis discussed with a physician through use of a "drop-down menu" system. Only diagnoses that fell within Depakote's indication were contained on the drop-down menu. Abbott managers instructed sales representatives to document in MAX the physician's name, the date of the call, and one of the on-label diagnoses,

even though the sales representatives were primarily detailing contact with physicians who were prescribing Depakote for off-label use.

3. Abbott And The PharmaCare Enterprise Trained Abbott's Sales Representatives To Off-Label Market Depakote

72. To conceal its wrongful conduct, Abbott conducted "off-site" (outside the Abbott Park location) training sessions for its sales representatives, using the PharmaCare Enterprise. These training sessions focused on maximizing Depakote sales through off-label promotion.

73. Because Abbott feared the implications of developing a standardized unlawful sales training program for Depakote at Abbott's headquarters, off-label training was provided by outside consultants, including training conducted by Dana Saffel, who at the time of the improper marketing activities, was the President & CEO of PharmaCare Strategies, Inc., located in Santa Rosa, Florida.

74. Ms. Saffel was an approved Abbott Speaker and trainer whose name appears on Abbott's official approved Speaker List starting in 2004.

75. Abbott paid Ms. Saffel $2,000 per day for each sales representative being trained. Abbott provided each manager with funds to train their sales staff; Ms. Saffel's payments came from such funds. Unlike other Abbott training programs which were held at Abbott Park, Illinois, Ms. Saffel's training occurred at a variety of locations across the United States.

76. Also as part of the Abbott training process, sales representatives were required to memorize and practice "role plays," which were scripted sales calls developed by Abbott to address physician objections to prescribing Depakote off-label for the purposes that Abbott sought to promote. Sales representatives practiced the Abbott role plays with other representatives in mock sales scenarios and were critiqued by Abbott managers.

77. Even after the training sessions were completed, Abbott required sales representatives to regularly practice role plays with supervisors over the telephone, so that Abbott's scripted off-label messages about Depakote became standardized. Abbott required sales representatives to perform telephone or "voicemail role plays" at least once or twice a month. Abbott even held contests to determine which representative had the best role play. The winning "voicemail role play" would often be distributed throughout the Abbott organization as a model.

78. Abbott further encouraged its sales representatives to deliver Abbott's carefully scripted message about the off-label use of Depakote by setting up monthly contests, within each of Abbott's district sales areas, that rewarded representatives with monetary awards based on, among other things, message delivery, appropriate use of sales materials, execution of speakers programs, and performance on "role plays" delivered over the phone on "call-ins."

79. Abbott trained sales representatives to use the bipolar mania "symptoms" chart found in their sales aids as a springboard to question physicians and other health care providers about their patient populations.

80. For example, sales representatives were instructed to point to the symptoms chart and ask physicians: "Do you treat patients in this nursing home with aggression, hostility etc.?" When the physician responded affirmatively, sales representatives were taught to segue into an off-label discussion of Depakote's use for agitation associated with dementia. In this way, Abbott trained its sales representatives to secure illegitimate sales of Depakote by obscuring the differences between bipolar mania and agitation associated with dementia, which have similar symptoms but are distinctly different conditions. According to the label, no patients over 65 were enrolled in the study upon which the Depakote mania indication was based.

81. Some versions of Abbott's Depakote sales aids, including the Skilled Nursing Kit, also include a variety of non-Depakote and non-drug related data, including disease statistics, to provide "cover" or as "pretext" for Abbott's promotion of Depakote off-label in certain health care settings, including skilled nursing homes, where the likelihood of capturing significant legitimate Depakote prescriptions is highly unlikely.

82. Also in furtherance of the scheme to illegally market Depakote, Abbott encouraged sales representatives to attend patient and/or caregiver support group meetings, sponsored by third party organizations, providing patients with information about treatment options and emotional support. Abbott encouraged sales representatives to use these support group meetings to promote Depakote off-label uses directly to patients and caregivers. Abbott also paid for and provided materials, including brochures, for sales representatives to give directly to those attending these support group meetings. For example, sales representatives promoted Depakote at programs given by the Alzheimer's Association at various locations called "Doctors and Desserts," which was a patient and caregiver support group meeting.

83. Abbott's activities were inconsistent with legal proscriptions against off-label marketing and with Abbott's written policies against off-label promotion, which were little more than distractions, or window dressing, aimed at misleading government enforcement officers.

84. Each member of the PharmaCare Enterprise financially benefited either through sales (Abbott), fees for training representatives in illegal marketing techniques (PharmaCare Strategies), or kickbacks (sales representatives at Abbott, doctors) for promoting the off-label use of Depakote.

4. Kickbacks: Abbott Paid Physicians To Induce Prescriptions And Hijacked CME And Other Ostensibly Independent Educational and Scientific Programs For The Unlawful Promotion of Depakote

85. Abbott's marketing strategy included the allocation of substantial resources to "educate" physicians and other health care professionals about off-label uses of Depakote Abbott promoted, including but not limited to, agitation associated with dementia. Funds were primarily used by sales representatives to pay physicians to spread Abbott's off-label marketing message to other physicians at speaker's programs, dinner lectures, CME classes, roundtables and other functions. Many of these off-label CME presentations were promoted through the CENE Enterprise and ABcomm Enterprise.

86. Abbott routinely set timetables for representatives to exhaust their allocated funds, often referred to as "war chest" funds, to ensure that representatives were devoting enough time and money to this key component of Abbott's off-label message. When sales representatives failed to exhaust their war chest funds, they received admonishments from Abbott managers in performance reviews. Sales representatives also attended dinners and other meetings that promoted the off-label use of Depakote set up by the CENE Enterprise.

87. Abbott encouraged sales representatives to approach to suggest that Abbott fund a speaker's dinner or program to be given by an Abbott selected local physician who routinely used Depakote off-label. Abbott called such doctors "thought leaders" or "champions" when they agreed to speak on off-label Depakote uses. Abbott provided compensation for the physician(s) either directly or indirectly as a payment to the intermediary, usually between $500 and $2,000 per physician, per speech.

88. For example, in Georgia, Abbott sales representatives approached Peachford Behavioral Health, Alzheimer's Association, and Georgia American Medical Directors

Association ("GAMDA"), among several other organizations, to suggest that Abbott sponsor a speaker on the use of Depakote to treat elderly patients for agitation associated with dementia, as well as other off-label uses of Depakote.

89. Abbott also provided funds to intermediaries to pay for the meals of physicians attending the lectures. Abbott Operating Procedures for Program Funding, in effect in March 2006, allowed for up to $125 per meal for attendees as long as there was a speaker.

90. Abbott recruited physicians who "championed" Abbott's off-label marketing efforts to be specially trained by Abbott's corporate marketing department. At the trainings, which typically occurred in luxury hotels in large cities including New York City, Chicago, and Atlanta, Abbott marketing managers provided physicians with talking points and other information over a three day period for use in lecturing at speaker's programs. Abbott rewarded these physicians by paying for travel, meals and the time associated with training. Abbott also conducted similar training sessions for physicians called "fly aways," which were all expense paid junkets to resort locations.

91. To accomplish the coaching, Abbott encouraged its sales representatives to personally pick up speakers from airports or other locations so that the physician could be reminded about Abbott's key selling messages.

92. The content of lectures given by Abbott's paid "champions" was so tightly monitored and controlled that if a physician failed to promote Depakote in the way that Abbott management desired, Abbott discontinued further speaking engagements for that "champion."

93. Management at Abbott's Illinois corporate headquarters were fully aware of the off-label Depakote speaker's program activities and events that Abbott financially underwrote. Abbott required its sales representatives to secure advance approval from Abbott headquarters

for payments for the events and the payments to doctors. Abbott sales representatives were given "ABcomm" specific funds to pay physicians to spread Abbott's off-label marketing message to other physicians at speaker's programs, dinner lectures, CMEs, roundtables, and other functions. For their efforts, sales representatives received between $20,000 to $30,000 per year in ABcomm and "war chest" funds.

94. For example, on May 7, 2002, Abbott management circulated off-label CME materials created by ABcomm to numerous Abbott sales representatives via email. The email stated that the CME materials "will allow more face time with our targets and deliver an effective message."

95. Attached to the May 7, 2002 email was an article titled "The Role of Mood Stabilizers in Treating Agitation: A Continuing Education Activity for Physicians, Pharmacists and Registered Nurses." The article was authored by Dr. Larry Tune and Dr. Andrew Weinberg, both members of CENE's faculty. The article was accompanied by a case study video and reference guide. All of the materials contained in the email were created by ABcomm through a grant from Abbott. All of the materials supported the off-label use of Depakote. For example, the video highlighted Dr. Tune and Dr. Weinberg sharing their clinical experience using Depakote to treat aggressive behavior in patients with dementia.

96. ABcomm funds were specifically used to promote the off-label use of Depakote. For example, Abbott sales representatives solicited a "CME Grant Request" which was addressed to ABcomm to have Dr. Craig Nelson speak for $1,500 on "Behavioral Disturbances and Alzheimer" at an Annual Symposium in Gatlinburg, Tennessee. Similarly, ABcomm disseminated numerous articles which were completely funded by grants from Abbott, including "Dementia Management: Regulations, Rules and Research." These are just two examples of

explicit requests Abbott sales representatives made to ABcomm to promote Depakote for agitation associated with dementia or other off-label uses of Depakote.

97. Abbott supervisors told sales representatives that it was legal to orchestrate speaker's programs through intermediaries like ABcomm, including selecting and coaching the physician speakers, as long as the appropriate Abbott Letter of Agreement (or "LOA") was signed by the physician and/or intermediary. Abbott's LOA states, among other things, that the intermediary or "provider," such as the Alzheimer's Association, "shall maintain full control over the planning, content, audience and implementation of the Program and over the selection of speakers, moderators, authors or other faculty of the program." Significantly, while these LOA documents were developed by Abbott, they failed to reveal the Company's actual involvement and control. In sum, the LOAs were no more than window dressing concealing Abbott's unlawful conduct.

98. To conceal the control Abbott exerted over the off-label content presented by its handpicked speakers at functions it orchestrated through intermediary organizations, Abbott's official procedures prohibited the conduct used by Abbott's sales and marketing staff to promote Depakote. For example, the 2006 version of Abbott's Operating Procedures for Program Funding requires that speaker program content about Abbott products "must be within labeling."

99. Abbott also paid some physicians to conduct studies within their own patient populations as a reward for prescribing large amounts of Depakote or in situations where Abbott managers believed the payment of physicians would encourage future Depakote prescriptions.

100. For example, Abbott paid between $8,000 - $10,000 to Dr. Hubert "Booney" Vance of Johnson City, Tennessee, to perform an off-label study of the use of Depakote for patients who had received Coronary Artery Bypass Graft Surgery and suffered from agitation

associated with dementia. Abbott employed a staff of physicians and other medical professionals referred to as "Medical Liaisons" whose purported job function was to provide specialized scientific and medical information to physicians. Medical Liaisons presented information to physicians that were not known by Abbott's sales representatives about Depakote including information about the drugs off-label uses. Abbott funneled money for this study and others like it through the budget for its Medical Liaisons in this instance, Abbott Medical Liaison James Stewart. Instead of using its Medical Liaisons to meet the legitimate needs of physicians seeking important patient efficacy and safety information about Depakote, Abbott used its Medical Science Liaisons to pay physicians to prescribe Depakote. Funding for Dr. Vance's study, through Abbott's Medical Liaison budget, was nothing more than a means to disguise an illegal *quid pro quo* payment to increase future Depakote prescriptions by Dr. Vance.

101. Abbott and the ABcomm Enterprise engaged in these efforts despite Abbott's own policy, which specifically proscribed such conduct.

102. Abbott's systematic kickback strategy ensured that the ABcomm Enterprise would have a constant and dependable group of medical professionals supporting its off-label Depakote marketing efforts.

C. COUNCIL FOR EXCELLENCE IN NEUROSCIENCE EDUCATION

103. As discussed above, in order to circumvent federal laws preventing off-label marketing, Abbott funded CENE to assist trained Abbott sales representatives in promoting the off-label use of Depakote. CENE, with funding from Abbott and assistance from ACCESS, maintained the CENE.com website. The 2002 version of CENE.com, a rather rudimentary site, stated on its home page that CENE was supported by an "unrestricted educational grant from Abbott Laboratories."

104. By 2004, the CENE website had been transformed into a slicker, multi-media site. It no longer disclosed links to Abbott in any obvious location. In the "About Us" section of the site, CENE.com stated that CENE "is an organization of nationally known clinicians in neurosciences, formed to develop a comprehensive, interactive and multi-dimensional continuing education program . . . in the rapidly growing field of neuroscience." It explained that CENE.com would offer CME programming on topics in "bipolar disorder, epilepsy, migraine, and behavioral disturbances associated with dementia" (all indicated or off-label uses of Depakote), but did not mention Abbott in the "About Us" section. Rather than reference any support from Abbott, the "About Us" page (and other pages of the website) now referenced ACCESS

105. The June 18, 2003 version of CENE.com appears to have referenced Abbott in only one place, the relatively obscure "Disclaimer" section of the website, where it stated, in pertinent part, that "CENE, Abbott Laboratories, and ACCESS Medical Group make no representations or warranties of any kind or nature with respect to the information found on this site [and] disclaim all representations and warranties . . ." In 2006, the warranty language was changed to remove Abbott's name altogether.

106. Abbott used CENE to promote the off-label use of Depakote to doctors through what appeared to be a legitimate medical education organization. CENE offered dozens of hours of free CME credits that could be earned by completing various activities on CENE's website. Additionally CENE offered symposia, webcasts, regional dinner meetings, monographs, and PowerPoint presentations.

1. Symposia

107. Each year, through the CENE Enterprise, Abbott held numerous symposia to help distribute the plethora of off-label materials created by ACCESS. The CENE Enterprise hosted symposia on topics including:

a. Effective Treatment of Behavioral Disturbances in the Elderly

b. The Impact of Treatment on Quality of Life

c. The Expanding Role of Mood Stabilizers

d. Mechanisms of Impulsivity

e. Aggression, Violence and Psychopathology: A Developmental Approach

f. Aggression in PTSD and Substance Use Disorders

g. The Impulsive-Aggression Symptom Domain in Personality Disorders

h. Diagnosis and Course of Bipolar Disorder in Children and Adolescents

i. Treatment of Children and Adolescents with Pediatric Bipolar Disorders

j. Novel & Maintenance Treatment Approaches in Pediatric Bipolarity

k. Juvenile Bipolar Disorder and Substance Use Disorders

l. Update on Treatment of Bipolar Depression

m. Epidemiology and Treatment of Mixed States

n. Update on Psychosocial Treatment of Bipolar Treatment

o. An Update on Psychopharmacology: Mood Stabilizers

p. Abnormal Mood Elevation

108. This extensive list of subjects makes no reference to epilepsy or seizures.

109. Each of these meetings and symposia offered Abbott another opportunity to promote the off-label use of Depakote to doctors and other health care professionals. Abbott

sales representatives often attended these meetings to ensure that doctors provided off-label messaging.

110. As Abbott expanded its off-label marketing efforts, the CENE Enterprise expanded its purported educational offerings concerning those off-label uses. For example, by January 4, 2003, CENE had added a presentation focusing on the use of Depakote for schizophrenia.

111. Abbott directed sales representatives to "coach" physicians who were newly selected to lecture at programs paid for, directly or indirectly, by Abbott through CENE. Abbott ensured that the physicians received "talking points," Abbott-prepared materials, and other key information about off-label uses of Depakote that Abbott wanted to be provided to the physicians attending the speaker's programs Abbott was promoting.

112. The CENE Enterprise annually hosted over 100 symposia across the United States. For example, in 2001 some of the symposia were organized in: Chicago, Illinois on June 23, Atlanta Georgia on September 9, Dallas, Texas on September 15, San Francisco, California on September 23, Orlando, New York, New York on October 5, Florida on October 13, and Los Angeles, California on October 19.

2. Webcasts

113. The CENE Enterprise also provided webcasts for individuals who could not attend conferences but wanted CME credit. Nearly all of the CENE webcasts were directed at promoting Depakote's off-label uses. For example, topics included:

- Innovations in the Treatment of Bipolar Disorder
- Impulsivity Spectrum Across Psychiatric Disorders
- Very Bad Behaviors: Impulsivity and Aggression

- Diagnosis and Treatment of Bipolar Disorder in Children and Adolescents
- The Role of Anticonvulsants as Adjunctive Treatment in Psychosis
- Managing Agitation and Aggression in the Elderly

114. One such webcast from a CENE.com symposium on June 23, 2005 in Chicago was entitled "One Brain – Many Disorders." The presentation was created through a joint sponsorship of ACCESS and CENE.

115. Before the widespread use of webcasts, the CENE Enterprise organized teleconferences termed "CATs." The CENE Enterprise planned to organize at least 250 CATs in 2001 alone.

3. Monographs

116. The CENE Enterprise also created monographs to promote the off-label use of Depakote. These monographs, which were created by ACCESS and funded by grants from Abbott, were made available on the CENE website and at symposia and other dinner meetings. Review of a monograph also offered CME credit for doctors.

117. One monograph first published in 2002 was titled "The Bipolar Spectrum: Rationale Polypharmacy." The guest editors of the monograph, Charles L. Bowden M.D. and James A. Wilcox, D.O., Ph.D., both provided "consultation services" to Abbott.

118. This monograph generally promoted the off-label use of Depakote concluding that "divalproex" (Depakote) was recommended to treat various phases and behavior dimension of bipolar disorder, making it appear Depakote was a suitable alternative to lithium, which is indicated for this condition.

119. The monographs also explicitly promoted the off-label use of Depakote including the following statements:

- "Divalproex has reduced agitation in a host of psychiatric disorders, and it appears to be particularly effective in the treatment of agitation associated with bipolar disorder or borderline personality disorder"
- "Divalproex, for example, has been shown to significantly improve global symptom severity and functioning measures in borderline personality disorder"
- "An open clinical trial of divalproex, conducted with 16 Vietnam veterans diagnosed with PTSD, yielded significant symptom relief for 10 subjects, especially with hyperarousal and hyperreactivity"

4. Dinner Meetings

120. The CENE Enterprise also held national and regional dinner meetings that were advertised as a way for doctors to meet their CME credit requirements. The true purpose of the dinner meetings was to promote the off-label use of Depakote.

121. For example, doctors were trained to identify and manage with Depakote impulsive aggressive behaviors in patients with bipolar disorder, borderline personality disorders, and psychosis.

122. If doctors were not available to travel to dinner meetings, CENE provided "Distance Learning" broadcasts. For example, on May 21, 2002 at 12:00pm eastern time, Dr. Leslie Citrome and Dr. Henry Nasrallah hosted a broadcast by CENE titled "Valproate Use in Schizophrenia: New Strategies to Optimize Efficacy."

123. As discussed below, Dr. Citrome and Dr. Nasrallah, like most if not all the other doctors listed or mentioned on CENE's website, received honoraria and funding from Abbott.

124. In 2001 alone, the CENE Enterprise planned over 25 CENE dinners in over 20 cities.

5. Faculty

125. Until at least 2006, CENE listed faculty members on the CENE website. In 2002 these faculty members included:

Daniel Anderson, MD	Jacobo E. Mintzer, MD
Ahmad A. Beydoun, MD	Dean K. Naritoku, MD
Manju T. Beier, PharmD	J. Craig Nelson, MD
Charles L. Bowden, MD	Lawrence Newman, MD
Joseph R. Calabrese, MD	John M. Pellock, MD
Deborah T.C. Cantrell, MD	Anton P. Porsteinsson, MD
Daniel E. Casey, MD	Alan M. Rapoport, MD
Kiki D. Chang, MD	William E. Reichman, MD
Kerry W. Cranmer, MD	A. David Rothner, MD
Andrew J. Cutler, MD	John F. Rothrock, MD
Lori A. Daiello, PharmD, BCPP	Gary S. Sachs, MD
Lori Davis, MD	Lon S. Schneider, MD
John DeToledo, MD	Stephen D. Silberstein, MD
Toufic A. Fakhoury, MD	Alan P. Siegal, MD
Frederick G. Freitag, DO	Clifford M. Singer, MD
Mark Frye, MD	Alan C. Swann, MD
Marie E. Gardner, PharmD	Pierre N. Tariot, MD
Joseph F. Goldberg, MD	David M. Treiman, MD
Donald M. Hilty, MD	Larry E. Tune, MD
Eric Hollander, MD	Basim M. Uthman, MD
Jeanne Jackson, MD	Karen Dineen Wagner, MD PhD
Terence A. Ketter, MD	Andrew D. Weinberg, MD, FACP
Robert A. Kowatch, MD	James W. Wheless, MD
Maria D. Llorente, MD	L. James Willmore, MD
Amy D. Lott, MD	Paul Winner, DO, FAAN, FAAP
Ninan T. Mathew, MD	

126. In 2003, the CENE.com website also provided a list of "Council Members." Those members included:

Charles L. Bowden, MD	Stephen D. Silberstein, MD
Joseph R. Calabrese, MD	Alan P. Siegal, MD
Daniel E. Casey, MD	Alan C. Swann, MD
Lori A. Daiello, PharmD, BCPP	Pierre N. Tariot, MD
Eric Hollander, MD	Karen Dineen Wagner, MD, PhD
J. Craig Nelson, MD	Andrew D. Weinberg, MD, FACP
John M. Pellock, MD	L. James Willmore, MD
Anton P. Porsteinsson, MD	Paul Winner, DO, FAAN, FAAP
Gary S. Sachs, MD	

127. Most, if not all, "faculty" and "council" members on the lists above received some form of grant, sponsorship, or other payment from Abbott, despite the fact that there is not a single mention of "Abbott" on the CENE.com biography for any of these individuals. Most of the faculty members were members of Abbott's speaker bureau or advisory board. The doctors listed as "faculty" and "Council Members" were aware of this designation.

128. Additionally, many of the doctors were paid to deliver slideshow presentations advocating off-label uses of Depakote. For example, one program entitled "The Role of Mood Stabilizers in the Treatment of Behavioral and Psychological Symptoms of Dementia" was "sponsored" by ACCESS Medical Group and made available through an "unrestricted educational grant from Abbott." Dr. Beier and Ms. Daiello, both members of the CENE "faculty," made the presentation. The slideshow directed doctors to use Depakote to address dementia related agitation in patients, an off-label use.

129. CENE.com is now essentially a dead website and it appears that CENE is a defunct organization. There have not been any updates on the CENE.com calendar of events since 2009. All references to Abbott and off-label uses of Depakote have been removed. No

information is available on the website about CENE's leadership or how to contact anyone at the organization. Similarly, CENE.com no longer has a listed faculty or any "educational material" available.

D. ABBOTT USES CONSENSUS CLINICAL PRACTICE GUIDELINES IT HAD FUNDED TO TOUT OFF-LABEL USE DEPAKOTE PRODUCTS

130. In 1998, Abbott developed a set of clinical practice guidelines ("CPG") for Depakote. CPGs, a summary of opinions consolidated into one source, are an important resource for doctors when considering which medications are appropriate for certain conditions. CPGs are typically formulated with a panel of experts who are members of a medical professional society or particular specialty.

131. In April 1998, McGraw Hill, with significant financial support from Abbott, published what purported to be an independent CPG entitled "Treatment of Agitation in Older Persons with Dementia, A Post Graduate Medicine Special Report" (the "1998 McGraw Report"). The 1998 McGraw Report was updated in May 2001 and January 2005 as part of a CME series on the treatment of dementia in the elderly. The updates to the 1998 McGraw Report were also funded by Abbott.

132. The 1998 McGraw Report was designed to increase the use of certain drugs by designing a set of treatment algorithms. A treatment algorithm provides a step-by-step decision tree which leads doctors or medical professional to recommend that a patient take a certain medication.

133. The 1998 McGraw Report, and its subsequent editions mandated the use of Depakote as a first-line of defense for dementia, even though Depakote was not approved for this use by the FDA. *Nowhere* do the guidelines disclose the financial ties that Abbott had to the publication. Once created, Abbott funded the promotion of these algorithms to health care

professionals. For example, Abbott created a condensed version of the 1998 McGraw Report which it passed out to doctors and other medical professionals.

134. Similarly, through a grant from Abbott, in 2001 ACCESS developed a pocket guide titled Dementia and Associated Behavioral Symptoms. The stated purpose of the guide was to provide an "easy-to-use" reference for health care professionals managing patients with dementia. The guide included Depakote as a "first line" drug for the treatment of long term agitation and sundowning in patients suffering from dementia. The guide was designed to promote the off-label use of Depakote to a broad, vulnerable patient population.

135. Abbott paid kickbacks to doctors to support the opinions within the 1998 McGraw Report and the 2001 pocket guide, deliberately engaging in widespread illegal, off-label marketing of Depakote.

E. ABBOTT PROMOTED THE PUBLICATION OF OFF-LABEL MARKETING MATERIALS

136. Abbott also promoted the off-label use of Depakote through "supplements" to medical journals. The supplements were often prepared in conjunction with a CME set up for Abbott through a Medical Education and Communication Company ("MECC") to present information that appeared to be free from pharmaceutical manufacturer influence.

137. In 1999, Abbott disseminated a supplement entitled, "Phenomenology and Treatment of Aggression Across the Psychiatric Illnesses: A Free Supplement to The Journal of Clinical Psychiatry," by Charles B. Nemeroff and Alan F. Schatzberg, and offered it free along with 4.5 hours of CME credit. Both authors were paid by Abbott to be consultants and received an Abbott grant, not disclosed in the supplement.

138. In February 2001, Abbott widely disseminated another supplement entitled "Bipolar Disorder & Impulsive Spectrum Letter," from the *Psychiatric Times*, including an

article "Treating Agitation in Dementia With Anticonvulsants." The supplement was prepared by Arline Kaplan, a writer for CME, Inc., Irvine California, with support by a grant from Abbott. The article was presented by Alan Siegal, an associate clinical professor of psychiatry at Yale, another paid consultant of Abbott. The article did not disclose the fact that Dr. Siegal was a paid consultant for Abbott. The article recommends the off-label use of Depakote. Alan Siegal was also a "Council Member" of CENE, involved in the CENE Enterprise.

139. On April 29, 2005, a supplement entitled "Case Studies: Management of Epilepsy In Persons With Intellectual/Developmental Disabilities With Or Without Behavioral Problems," was released after being sponsored by Abbott. The supplement was authored by two researchers paid by Abbott, Dr. Eric Hollander and Dr. Theodore Sunder.

140. These supplements provided another opportunity for Abbott to promote unapproved uses of Depakote. Abbott knew recommendations by fellow practitioners, particularly respected practitioners, were highly regarded by most physicians and were particularly effective in getting doctors to change prescription behavior.

141. Additionally Abbott engaged in "peer selling." Doctors would be trained to sell Depakote to other doctors in the guise of educational or professional programs. This marketing strategy, however, could only succeed if it appeared that the doctor-spokespersons were promoting off-label Depakote because they had independently determined that such treatment was beneficial for their patients, not because they were actually the mouthpieces of a drug company marketing plan. Throughout its off-label promotion campaign, Abbott hid its involvement in the promotion of off-label information and misled physicians to whom it was peer selling into believing that the physicians who promoted Depakote were independent.

F. ABBOTT OFF-LABEL MARKETED DEPAKOTE FOR A VARIETY OF NON-APPROVED ILLNESSES

142. Through the CENE Enterprise, PharmaCare Enterprise, and ABcomm Enterprise, Abbott was able to promote Depakote's off-label use for a variety of non-approved illnesses.

1. Bipolar Depression in Adults and Children

143. Abbott encouraged its sales representatives to promote Depakote for childhood and adult bipolar depression. Depakote is indicated for mania associated with bipolar disorder in adults, but not depression associated with bipolar disorder ("bipolar depression") or maintenance therapy of bipolar disorder. Depakote is not indicated for children with any type of bipolar disorder and has not been shown to be effective for this use. A pediatric study to evaluate the efficacy of Depakote ER for mania in patients aged 10-17 years of age, which is discussed in some detail in Depakote's Prescribing Information, failed to establish efficacy of Depakote for this patient population.

144. Bipolar patients "cycle" between "manic" and "depressed" states. Statistically, "bipolar disorder I" patients spend more time in the "depressed" phase than in the "manic" phase. Because the market for treating the "depressed" phase of "bipolar I" was larger than the market for treating the "manic" phase of "bipolar I," Abbott seized the opportunity to off-label market Depakote DR and Depakote ER for the non-indicated bipolar depression.

145. Lamictal is indicated for maintenance treatment of "bipolar I disorder," to delay the time to occurrence of mood episodes - depression ("bipolar depression"), mania ("bipolar mania"), hypomania, and mixed episodes) - while Depakote ER is indicated for acute manic and mixed episodes associated with bipolar disorder. Depakote ER is not indicated for "maintenance" of bipolar mania. The package insert states that efficacy for bipolar mania has not been studied for periods greater than three weeks of use.

146. Abbott paid Dr. Gami of Emory University $2,000 to $3,000, either directly or indirectly, to provide a lecture to physicians at Peachford Mental Health about prescribing Depakote off-label for bipolar depression.

147. Abbott also paid Dr. Joseph Bona $1,500 to discuss bipolar depression at the Cobb County (Georgia) Community Service Board. Dr. Bona was selected to speak by Abbott because he was the clinical director at the DeKalb Community Service Board, a public provider of services for patients experiencing mental illnesses, developmental disabilities, and addiction illnesses that had over 20 locations in the metropolitan Atlanta area.

148. Abbott also used the medical journal supplements concerning bipolar disorder discussed above to support their promotion of Depakote for the treatment of bipolar disorder generally.

149. As discussed above, sales representatives were trained to off-label market Depakote for bipolar depression through use of "role plays" developed by Abbott. Using guided questions and answers, the "role plays" showed Abbott representatives how to overcome physician objections to using Depakote off-label over Lamictal.

150. Abbott believed that Lamictal (another anticonvulsant) was outselling Depakote in the bipolar market because patients typically do not seek treatment when they are in the "manic phase" of bipolar disorder (*i.e.*, at the time the patient feels euphoric). Abbott, therefore, sought to capitalize on the notion that just treating the depressive phase of bipolar disorder with Lamictal was insufficient because, eventually, the patient would swing into the manic phase of bipolar disorder.

151. For children, Depakote sales representatives were trained to focus on a negative side effect of Lamictal, *i.e.*, Stevens-Johnson syndrome, a life-threatening skin disease.

152. Sales representatives were taught to deal with objections by psychiatrists to using Depakote to treating children with bipolar disease. For example, at Cobb County Mental Health Center ("Cobb County"), Drs. Glover and Carter explained to sales representatives that they used Lamictal (off-label) for children suffering from bipolar disease because Lamictal is indicated for use in children over the age two with epilepsy and for adult bipolar depression. Sales representatives urged Drs. Glover and Carter try Depakote instead of Lamictal because Depakote was indicated for children ten years and older for epilepsy and, therefore, the drug was purportedly safe because it was "the same molecule, just a different indication."

153. Abbott taught its sales representatives to use the term "different indication" to obscure the truth (*i.e.*, that Depakote did not have any indication for use in bipolar depression, ADHD, and/or other psychiatric or behavioral issues in children).

154. Sales representatives were also trained to cite a study by Dr. Cameron Quanbeck, *et al.*, called "Clinical and Legal Correlates of Inmates with Bipolar Disorder at Time of Arrest," which indicates that at the time of criminal arrest 74% of bipolar patients are in the manic phase of bipolar disorder. *See* J. Clin. Psychiatry 2004; 65(2); 198-203. This data was also included in a May 2006 Abbott Sales Aid called "Grounded In Dependability."

155. Sales representatives were trained to "cherry pick" information from several other studies to discredit clinical trials cited in GlaxoSmithKline's Lamictal sales aids in order to gain off-label market share for use of Depakote in bipolar depression.

156. Abbott sales representatives were encouraged to contrast Depakote's lower cost and higher likelihood of reimbursement by private and Government payors with Lamictal, which was much more costly and less likely to be reimbursed.

157. Abbott instructed its sales representatives to provide materials, including videotaped or recorded speaker programs (usually on compact disc) produced by Abbott for CME lectures, discussing the off-label use of Depakote in children. The physician could obtain these materials directly from Abbott, by filling out request cards provided by sales representatives (if initiated by the physician), but more frequently sales representatives were directed to distribute these recorded programs routinely to physicians during sales calls.

158. After Depakote DR's approval to treat acute bipolar mania in 1995, Depakote sales surpassed sales of lithium (FDA-approved for bipolar mania, bipolar depression and maintenance treatment of bipolar disorder generally), becoming the most-prescribed drug for treatment of bipolar disorder.

159. The CENE Enterprise played a critical role in these off-label promotion efforts by creating and distributing slideshows advocating the use of Depakote for bi-polar disorder including: 1) "Update on Treatment of Bipolar Depression"; 2) Treatment of Children and Adolescents with Pediatric Bipolar Disorders; 3) "Novel & Maintenance Treatment Approaches in Pediatric Bipolarity"; and 4) "Diagnosis and Course of Bipolar Disorder in Children and Adolescents"

160. These slideshows were presented all over the country by CENE faculty paid by Abbott. The slideshows were also available on CENE.com.

161. CENE webcasts also promoted the off-label use of Depakote for bipolar patients including a webcast entitled "Innovations in the Treatment of Bipolar Disorder." This webcast was made available for free CME credit on the CENE.com website.

2. Developmental Delay, Attention-Deficit Disorder and Psychiatric Disorders in Children Under Eighteen Years of Age

162. Abbott also sought to increase Depakote sales by targeting children with problems including attention-deficit hyperactivity disorder ("ADHD"), developmental delay ("DDD" formerly known as "MRDD"), psychiatric disorders, and/or behavioral problems. Depakote ER is indicated for children ten years of age and older for epilepsy, but not for developmental delay, ADHD, psychiatric disorders, or behavioral problems in children of any age. There is no credible evidence that Depakote is effective for treating any of these disorders.

163. The direction and strategy for off-label marketing Depakote to children with MRDD came from Abbott's Marketing Department at the Company's headquarters.

164. Abbott managers directed sales representatives to off-label market Depakote for use in children through the Company's Specialty Accounts division.

165. Abbott devised a "boot strap" strategy justifying the off-label marketing of Depakote for the treatment of developmental delay in children. The strategy flowed from justifying the use of a childhood epilepsy drug as a medication to address developmental delay. Abbott knew that mental health centers treated children with developmental delay and, thus, trained its Depakote sales representatives to detail the pediatricians with sales aids purportedly demonstrating that "epilepsy occurs in 20% to 30% of children with intellectual/developmental disabilities."

166. These epilepsy statistics not only provided cover for Abbott's off-label promotion to children served by community Mental Health Centers, but also provided a springboard for Abbott's sales representatives to discuss Depakote's use in mitigating symptoms or behaviors associated with developmental delay, much in the same way that Abbott used the overlapping

symptoms of bipolar mania and agitation associated with dementia to justify Depakote's off-label use for elderly patients.

167. Abbott, through the CENE Enterprise, targeted children to expand the off-label use of Depakote, through the CENE symposia: Juvenile Bipolar Disorder and Substance Use Disorders; Diagnosis and Course of Bipolar Disorder in Children and Adolescents; and Aggression, Violence and Psychopathology: A Developmental Approach.

3. Symptoms Associated With Narcotic Drug Withdrawal and Addiction

168. Abbott also directed its sales representatives to off-label market Depakote for symptoms associated with narcotic drug withdrawal and addiction, although there was no evidence of the drug's efficacy in treating these symptoms.

169. At Cobb County Mental Health Center, Abbott provided funding for off-label speaker events where a physician, Dr. Christopher Riddell, from WellStar Behavioral Health, LLC, was paid either directly or indirectly by Abbott to advocate the use of Depakote for treating symptoms associated with narcotic drug withdrawal.

170. Abbott produced a slide presentation and/or CME materials on Depakote's off-label use for narcotic drug withdrawal symptoms, available by CD Rom and on the CENE.com website. This slide presentation and CME materials were also provided by Abbott to physicians when being paid to lecture on Depakote's off-label uses.

171. Abbott also paid Dr. Tommie Richardson to provide a CME on the "Use of Anticonvulsants in Detoxification from Alcohol and Drugs," which was given on April 5, 2005 at the Cobb Community Services Outpatient Services Center in Marietta, Georgia.

172. As discussed above, the CENE Enterprise also promoted the off-label use of Depakote for substance and alcohol abuse through the slide show presentation "Aggression in PTSD and Substance Use Disorders."

4. Psychosis

173. Abbott also trained its sales representatives to off-label market Depakote for psychosis (hallucinations, hearing voices, etc.), which is not indicated on Depakote's label. In several Abbott sales aids, including one entitled "Grounded in Dependability," published in September 2005, Abbott presented a study analyzing Depakote vs. Olanzapine (an anti-psychotic) in a "psychotic subgroup." Abbott instructed its sales representatives to use the data in this sales aid to off-label market Depakote for psychosis, even though there was no credible evidence that it was effective for this use.

174. Abbott also provided its sales representatives an approved reprint of a study Abbott sponsored entitled, "Effect of Divalproex Combined with Olanzapine or Risperdone [an anti-psychotic] in Patients with an Acute Exacerbation of Schizophrenia," Daniel E. Casey,[2] *et al*. Neuropsychopharmacology (2003) 28, 182-192 (the "Casey Study"), to use in detailing physicians treating patients with psychosis or schizophrenia. The study examined the use of divalproex with an antipsychotic agent (*i.e.*, Risperdone or Olanzapine) in patients hospitalized for acute exacerbation of schizophrenia.

175. Abbott trained its sales representatives to use the Casey Study to promote Depakote's adjunct use with either Olanzapine or Risperdal to treat psychosis or schizophrenia, even though Depakote is not FDA-approved for treatment of either of these disorders.

176. Abbott also used the medical journal supplements it surreptitiously sponsored in order to support these off-label use of Depakote.

[2] Dr. Casey was listed as part of CENE's faculty and CENE Council Member.

177. As discussed above, the CENE Enterprise helped facilitate these efforts with a presentation it promoted entitled "Anticonvulsants as Adjunctive Treatment in Psychosis."

5. Maintenance Dose for Elderly in Agitation Associated With Dementia

178. Abbott also trained its sales representatives to provide instructions for maintenance dosing of Depakote for agitation associated with dementia, even though there is no credible evidence of Depakote's efficacy for this disorder and no FDA-approved dose of Depakote for this problem.

179. These targeted patients - elderly persons suffering from dementia - were unable to give informed consent before being placed on Depakote for unapproved uses at an unapproved dosage level.

180. Abbott used the 1998 McGraw Report discussed above, supported and promoted by doctors receiving kickbacks, to promote Depakote for use in treating dementia-associated agitation.

181. Abbott based its suggested dose for this disorder on a study entitled "Valproate Therapy for Agitation in Dementia," A.P. Porsteinsson, *et al.*, Am J Geriatr Psychiatry, 2003; 11:4, purportedly calculating a therapeutic dose of Depakote Sprinkles at 845 milligrams.

182. If a physician chose to use Depakote DR, Abbott instructed its sales representatives to suggest an approximate dose of Depakote DR, which was also 845 milligrams, even though the formulations of Depakote DR and Depakote Sprinkles are not identical.

183. After 2000, when Depakote ER was first approved only for prophylaxis of migraine, Abbott directed sales representatives to use the Porsteinsson data on Sprinkles (suggesting 845 milligrams), but to promote an increased dose of Depakote ER of approximately 1,000 milligrams.

184. Abbott trained its sales representatives to suggest this increased dose, even though (or maybe because) it caused elderly patients to sleep all day. Abbott did so despite the warning on the label, which stated that starting doses should be decreased in elderly patients due to a greater sensitivity to somnolence.

185. Indeed, the label specifically instructs physicians treating geriatric patients for seizure disorders to lower the initial dose and to increase the dose more slowly, with regular monitoring, and reduce or discontinue Depakote in patients with excessive somnolence. The label also expressly states that there is no evidence for safety or efficacy for migraine prophylaxis or mania in this population.

186. As discussed above, the CENE Enterprise helped facilitate these efforts with a webinar titled "Managing Agitation and Aggression in the Elderly."

G. ABBOTT PROMOTED DOSING INSTRUCTIONS AND FORMULATIONS OF DEPAKOTE OUTSIDE DEPAKOTE'S PACKAGE INSERT

187. Abbott also trained its sales representatives to provide "rapid loading dose" instructions for Depakote DR in treating acute mania, where the patient was exhibiting extreme symptoms. Physicians resorted to this strategy in hospitals or acute care settings where patients with acute psychiatric problems were treated urgently or emergently and only Depakote DR was available. Abbott trained its sales representatives to use sales aids and CME materials, originally produced by Abbott as educational materials for physicians, as sales aids to convince physicians to "rapid load" Depakote DR even though there have never been dosing instructions in Depakote's package insert for "rapid loading," and there is no credible evidence of Depakote's efficacy in this setting.

188. Abbott trained its sales representatives to detail physicians on rapid loading by using a February 2003 CME material (on audio CD and accompanying booklet) entitled "Bipolar

Disorder: Treatment Guidelines and Their Implications for Your Practice" by Dr. Robert M.A. Hirschfeld.

189. The CME materials discussed using 30 milligrams per kilogram of body weight (i.e. higher than the 20mg/kg used by physicians in urgent circumstances) for patients suffering from acute manic episodes. As a chart on page seventeen of the CME booklet showed, a 150 pound person would receive a loading dose of 2000 mg of Depakote DR.

190. Depakote DR's package insert, however, does not reference any "rapid loading" dose. The information that Abbott provided concerning "rapid loading" was potentially harmful to patients, especially because rapid loading had not been adequately studied or vetted through the FDA approval process.

191. The CENE.com website for physicians provided rapid loading dose instructions, used by Abbott's sales representatives to promote off-label uses. Abbott managers and trainers instructed sales representatives to use the off-label information, even when the physician did not solicit it.

192. Abbott paid Dr. Stephen Stall, a California-based physician, to produce a CME Video on Depakote "rapid loading." Part of Dr. Stall's presentation discussed how public health care providers are able to save money using Depakote over atypical antipsychotics for acutely manic patients.

VI. GOVERNMENTAL AND OTHER ACTIONS CONCERNING ABBOTT'S OFF-LABEL PROMOTION

193. Pharmaceutical companies who violate the FDCA by improperly off-label marketing their drugs often do so in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("False Claims Act"). The False Claims Act prohibits knowingly or recklessly submitting false claims to the Government, or causing others to submit false claims. In this

context, anyone who causes a claim for payment for a drug to be submitted to the federal government in circumstances where the prescription is for an off-label use that was procured through marketing practices that violate the FDCA also violates the False Claims Act.

194. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also applies to the state Medicaid programs, prohibits individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce the referral of business that is reimbursable under the federal healthcare programs. Medicare regulations directly prohibit providers from receiving remuneration paid with the intent to induce or reward the prescribing of pharmaceuticals. The offense is a felony punishable by fines or imprisonment, and can also cause the levying of civil penalties.

195. Between October 2007 and January 2010, relators filed four sealed *qui tam* complaints against Abbott pursuant to the False Claims Act, 31 U.S.C. § 3730(b), detailing this multi-faceted scheme by which Abbott illegally marketed Depakote. The Company's scheme worked and sales of Depakote rocketed to over $1.4 billion per year while the governments were defrauded by resulting overcharges totaling millions of dollars.

196. On February 1, 2011, the United States government and the governments of the States of California, Georgia, Indiana, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Texas, Wisconsin and the Commonwealths of Massachusetts and Virginia intervened in all four *qui tam* actions, followed by the State of Delaware on April 6, 2011, all seeking to recover treble damages and civil penalties under the Federal and State False Claims Acts. On February 1, 2011, all four *qui tam* actions were unsealed.

197. These actions, styled *United States ex rel. McCoyd v. Abbott Labs.*, Civil Action No. 1:07cv00081, and *United States ex rel. Spetter v. Abbott Labs.*, Civil Action No. 1:10cv00006, both filed in the United States District Court for the Western District of Virginia; *United States ex rel. Mulcahy, et al. v. Abbott Labs.*, Civil Action No. 1:09cv00054, filed in the United States District Court for the District of Columbia; and *United States ex rel. Dietzler v. Abbott Labs.*, Civil Action No. 1:09cv00051, filed in this Court, were all transferred to the United States District Court for the Western District of Virginia and consolidated with *United States ex rel. McCoyd v. Abbott Labs.*, Civil Action No. 1:07cv00081, on May 20, 2011.

198. On May 7, 2012, Abbott agreed to pay $1.6 billion to resolve criminal and civil claims that the Company engaged in the unlawful off-label promotion of Depakote. Abbott pleaded guilty to misbranding Depakote by promoting the drug to control agitation and aggression in elderly dementia patients and to treat schizophrenia when neither of these uses was FDA approved. In the statement of facts filed in the criminal action, Abbott admitted that, from 2001 through 2006, the company marketed Depakote in combination with atypical antipsychotic drugs to treat schizophrenia, even after its clinical trials failed to demonstrate that adding Depakote was any more effective than an atypical antipsychotic alone for that use. The civil settlement agreement, which Abbott signed, contends that Abbott illegally marketed Depakote by:

a. knowingly promoting the sale and use of Depakote for uses that were not approved by the Food and Drug Administration as safe and effective ("unapproved uses"), including behavioral disturbances in dementia patients, psychiatric conditions in children and adolescents, schizophrenia, depression, anxiety, conduct disorders, obsessive-compulsive disorder, post-traumatic stress disorder, alcohol and drug withdrawal, attention deficit disorder, autism, and other psychiatric conditions. Some of these unapproved uses were not medically accepted indications for

which the United States and state Medicaid programs provided coverage for Depakote. This promotion included, in part:

i. making false and misleading statements about the safety, efficacy, dosing, and cost-effectiveness of Depakote for some of these unapproved uses;

ii. marketing Depakote to health care professionals to control behavioral disturbances in dementia patients in nursing homes by claiming that Depakote was not subject to certain requirements of the Omnibus Budget Reconciliation Act of 1987 (OBRA) designed to prevent the use of unnecessary drugs in nursing homes and that this use of Depakote would help nursing homes avoid the administrative burdens and costs of complying with OBRA regulatory restrictions applicable to anti psychotics.

b. offering and paying illegal remuneration to health care professionals and long term care pharmacy providers to induce them to promote and/or prescribe Depakote and to improperly and unduly influence the content of company sponsored Continuing Medical Education programs, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. *§* 1320a-7b(b).

VII. FRAUDULENT CONCEALMENT AND TOLLING OF STATUTES OF LIMITATION

199. The off-label marketing scheme depended on Abbott's concealment of its involvement in the off-label promotion of Depakote. Indeed, the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise were created for the purpose of making it appear to the public that Abbott itself was not involved in promoting off-label use.

200. Additionally, and as described above, Abbott had the CENE Enterprise, PharmaCare Enterprise, and ABcomm Enterprise conduct off-label promotion through seemingly legitimate continuing medical education seminars, medical journal supplements, and other medical education events.

201. As also described above, Abbott's involvement in these activities was hidden because Abbott hid its financial connections to participating physicians by using intermediaries.

These activities and others described above concealed Abbott's off-label promotional activities and Plaintiffs could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Much of the scheme – to this day – remains concealed by Abbott.

202. Any applicable statutes of limitation have been tolled by Abbott's knowing and active concealment and denial of the facts alleged herein. Plaintiffs and the other Class and Subclass members have been kept in ignorance of vital information essential to the pursuit of these claims without any fault or lack of diligence on their part. Plaintiffs and the other Class and Subclass members could not reasonably have discovered the fraudulent nature of Abbott's conduct. Accordingly, Abbott is estopped from relying on any statute of limitations to defeat any of Plaintiffs' or the other Class and Subclass members' claims.

VIII. ABBOTT'S MOTIVES

203. Abbott's motive in creating and operating the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise described herein was to obtain additional revenues from the illegal and fraudulent off-label marketing and sale of Depakote, which would have had significantly lower sales had it been sold only for the approved indications. Due to its off-label marketing and conduct described herein, Abbott ultimately increased its annual sales of Depakote to a high of $1.5 billion in 2007, the year before Abbott lost patent exclusivity for some forms of Depakote.

IX. CAUSATION AND DAMAGES

204. The scheme was designed to cause, and did cause, Plaintiffs and the other Class and Subclass members to pay for Depakote prescriptions to treat conditions for which the drug is not FDA approved and for which there was no reliable scientific evidence that Depakote was effective. Patients, including those whose prescription drug charges were paid by class members, and who were prescribed the drug for non-approved uses received no greater relief

from, or treatment of, their medical conditions than they would have received from a placebo and/or were subject to additional side effects. Absent Abbott's improper conduct, Plaintiffs and the other Class and Subclass members would not have paid for such Depakote prescriptions.

205. The scheme was designed to cause, and did cause, Plaintiffs and the other Class and Subclass members to pay for Depakote prescriptions when there were alternative medications that were cheaper, more effective, or had fewer side effects than Depakote.

X. USE OF THE MAILS AND WIRES

206. During the Class Period, Abbott used mail and interstate wire communications to create and manage its fraudulent scheme. Abbott's scheme involved national marketing and sales plans and programs – including telephonic "role playing" – and encompassed physicians and victims across the country.

207. Abbott's use of the mails and wires to perpetrate its scheme included:

- Mailing marketing materials about the off-label uses of Depakote to doctors across the country;
- Communications and financial payments between Abbott, complicit physicians, and physician "authors" discussing and relating to the publication of articles or medical journal supplements touting off-label uses of Depakote for which the drug is not safe and medically efficacious;
- Communications and financial payments between Abbott and physician participants relating to the production of each and every event put on by the PharmaCare Enterprise, including communications concerning the content of the presentations to be made at such events;

- Webcasts, slideshows, and symposia arranged and promoted by the CENE Enterprise which made misleading statements about use of unapproved indications to other physicians, including but not limited to statements that Depakote was effective for the treatment of off-label conditions;
- Teleconferences arranged by Abbott at which complicit participating physicians made false and misleading statements about use of unapproved indications to other physicians, including but not limited to statements that Depakote was effective for the treatment of off-label conditions;
- Payments transported through the mail and the wires to physicians attending events held by the CENE Enterprise, PharmaCare Enterprise, and ABcomm Enterprise in order to induce the physicians to prescribe Depakote; and
- Communications, payments and monetary transfers using the wires to receive and distribute the proceeds of Abbott's improper scheme.

208. In addition, Abbott has communicated by United States mail and telephone with various local sales representatives, complicit physicians, and other members of the CENE Enterprise, PharmaCare Enterprise, and ABcomm Enterprise in furtherance of Abbott's schemes.

XI. SCOPE OF THE ALLEGATIONS

A. TIME

209. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of Depakote, occurred from 1998 through 2012.

B. GEOGRAPHIC SCOPE

210. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of Depakote, took place throughout the United States and District of Columbia, as

well as various other territories and foreign countries. Although many of Abbott's sales and marketing strategies were executed through sales representatives and sales managers, those strategies were developed and disseminated by and from Abbott's Illinois headquarters.

XII. CLASS ACTION ALLEGATIONS

211. Plaintiffs bring this action pursuant to Rules 23(a), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of themselves and all others similarly situated. Plaintiffs seek to represent a Class (the "Nationwide Class" or the "Class") initially defined as:

> All third party purchasers in the United States and its territories who, during the period from 1998 through 2012, reimbursed and/or paid some or all of the purchase price for Depakote for indications not approved by the FDA.

212. Additionally, Plaintiffs bring this action on behalf of three separate State Subclasses.

213. Plaintiff UFCW brings this action on behalf of an Illinois Subclass (the "Illinois State Subclass") defined as:

> All third party purchasers in the State of Illinois who, during the period from 1998 through 2012, reimbursed and/or paid some or all of the purchase price for Depakote for indications not approved by the FDA.

214. Plaintiff Hillman Center brings this action on behalf of a New York Subclass (the "New York State Subclass") defined as:

> All third party purchasers in the State of New York who, during the period from 1998 through 2012 reimbursed and/or paid some or all of the purchase price for Depakote for indications not approved by the FDA.

215. Plaintiff Local 404 brings this action on behalf of a Massachusetts Subclass (the "Massachusetts State Subclass") defined as:

> All third party purchasers in the Commonwealth of Massachusetts who, during the period from 1998 through 2012, reimbursed and/or paid some or all of the purchase price for Depakote for indications not approved by the FDA.

216. Excluded from the Class and State Subclasses are (a) Abbott, AbbVie, and any entity in which any Defendants have a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from the Class and State Subclasses are any judge to whom this case is assigned, together with any relative of such judge within the third degree of relationship, and the spouse of any such person.

217. This action has been brought and may properly be maintained on behalf of the Class and State Subclasses proposed herein under the criteria of Rule 23 of the Federal Rules of Civil Procedure.

218. **Numerosity – Federal Rule of Civil Procedure 23(a)(1).** The members of the Class and State Subclasses are so numerous and geographically dispersed that individual joinder of all Class members is impracticable. While Plaintiffs are informed and believe that there are not less than tens of thousands of members of the Class and State Subclass members, the precise number of Class and State Class members is unknown to Plaintiffs, but likely can be ascertained from Abbott's books and records. Class and State Subclass members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. mail, electronic mail, Internet postings, and/or published notice.

219. **Commonality and Predominance – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3).** This action involves common questions of law and fact, which predominate over any questions affecting individual Class and State Subclass members, including, without limitation:

a. Whether Depakote is not medically necessary for uses not approved by the FDA;

b. Whether the CENE Enterprise, PharmaCare Enterprise, ABcomm Enterprise, and Abbott engaged in a fraudulent and/or deceptive scheme of improperly marketing and selling Depakote for conditions for which it is not safe or medically efficacious;

c. Whether the CENE Enterprise, PharmaCare Enterprise, ABcomm Enterprise, and Abbott engaged in a fraudulent and/or deceptive scheme of improperly marketing and selling Depakote to treat conditions for which the drug was not approved by the FDA;

d. Whether CENE Enterprise, PharmaCare Enterprise, ABcomm Enterprise, and Abbott coached or instructed physicians how to conceal the off-label nature of Depakote prescriptions on claim forms submitted by or to Plaintiffs and the other Class and State Subclass members;

e. Whether it was the policy and practice of CENE Enterprise, PharmaCare Enterprise, ABcomm Enterprise, and Abbott to prepare, fund and publish materials, presentations, and webcasts which contained false information and misrepresentations regarding off-label uses for Depakote;

f. Whether Defendants are liable to Plaintiffs and the other Class and Subclass members for damages caused by Abbott's conduct actionable under the RICO statute;

g. Whether Abbott engaged in a pattern of practice that directly caused Plaintiffs and other Class and Subclass members to pay for Depakote prescriptions that were for non-medically necessary uses;

h. Whether Abbott engaged in a pattern of practice that directly caused Plaintiffs and other Class and Subclass members to pay for Depakote prescriptions that were for non-FDA approved uses;

i. For each of the Subclasses, whether as a result of its practices described herein Abbott was unjustly enriched; and

j. For the Illinois State Subclass and New York States Subclass, whether as a result of its practices described herein, Abbott violated the deceptive trade act statutes of New York and Illinois.

220. **Typicality – Federal Rule of Civil Procedure 23(a)(3).** Plaintiffs' claims are typical of the other Class and State Subclass members' claims because, among other things, all Class and State Subclass members were comparably injured through Abbott's wrongful conduct as described above.

221. **Adequacy of Representation – Federal Rule of Civil Procedure 23(a)(4).** Plaintiffs are adequate Class and State Subclass representatives because their interests do not conflict with the interests of the other members of the Class and State Subclasses they respectively seek to represent; Plaintiffs have retained counsel competent and experienced in complex class action litigation; and Plaintiffs intend to prosecute this action vigorously. The Class and State Subclasses' interests will be fairly and adequately protected by Plaintiffs and their counsel.

222. **Superiority – Federal Rule of Civil Procedure 23(b)(3).** A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by Plaintiffs and the other Class and State

Subclass members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Abbott, so it would be impracticable for Class and State Subclass members to individually seek redress for Abbott's wrongful conduct. Even if Class and State Subclass members could afford individual litigation, the court system could not. Individualized litigation creates a potential for inconsistent or contradictory judgments, and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

CLAIMS ALLEGED

First Claim For Relief
Violation of 18 U.S.C. § 1962(c)
(Brought on Behalf of the Nationwide Class)

223. Plaintiffs incorporate by reference each of the above paragraphs of this Complaint as though fully stated herein.

224. Abbott is a "person" within the meaning of 18 U.S.C. § 1961(3), who conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1982(c).

225. The CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise are all associations-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting each of Abbott, including its employees and agents, and the persons identified above.

226. The CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise were ongoing organizations that functioned as continuing units. The CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise were created and/or used as a tool to

effectuate a pattern of racketeering activity. Abbott is a "person" distinct from the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise.

227. Abbott established the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise to distance itself from illegal off-label marketing and to evade federal regulations concerning off-label promotion.

228. The CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise engaged in and affected interstate commerce, because, among other things, they marketed, sold, purchased, or provided Depakote to thousands of individuals throughout the United States.

229. Abbott has exerted control over the off-label promotion of Depakote and has participated in the operation or management of the affairs of the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise, through at least the the following actions:

k. Exerting direct control over the information and content disseminated to doctors through webcasts, slide shows, dinners, and symposium;

l. Exerting direct control over the creation and distribution of marketing and sales materials sent to physicians and the doctors attending events throughout the United States; and

m. Placing its own employees and agents in positions of control in the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise.

n. Conducting and participating in the affairs of the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), § 1952 (use of interstate facilities to conduct unlawful activity), and state bribery statutes.

230. As detailed above, Abbott's pattern of racketeering activity includes acts indictable as mail fraud under 18 U.S.C. § 1341 and wire fraud under 18 U.S.C. § 1343. Abbott's fraudulent scheme consisted of, among other things: (a) deliberately misrepresenting the uses for which Depakote was safe and effective so that Plaintiffs and the other Class members paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective; (b) providing webinars, slide shows, symposia and CME dinners containing or discussing false and/or misleading information upon which physicians, Plaintiffs, and members of the Class relied upon when choosing to prescribe or pay for Depakote; (c) actively concealing, and causing others to conceal, information about the true safety and efficacy of Depakote to treat conditions for which it had not been approved by the FDA; (d) intentionally misrepresenting and concealing Abbott's role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Depakote to off-label markets; and (e) intentionally misrepresenting and concealing the financial ties between Abbott and other participants in the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise.

231. In implementing the fraudulent scheme, Abbott was acutely aware that Plaintiffs and the other Class members depend on the honesty and integrity of Abbott in representing the medical efficacy of Depakote's uses. It is impractical and unduly expensive for Plaintiffs and/or the other Class members to perform their own clinical trials or assemble all known medical evidence relating to Depakote's uses. Plaintiffs and the other Class members also rely on federal law obligating Abbott to provide fair and balanced information about their drug products and reasonably presume that when such marketing of Depakote was conducted, it complied with Abbott's obligations under federal law.

232. Abbott's scheme was calculated to ensure that Plaintiffs and the other Class members would pay for Depakote to treat a wide variety of uses for which Abbott knew Depakote had not been shown to be efficacious.

233. The CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise used the mails and wire to implement the scheme. For example, the planning and coordination of CME events, webinars, and presentations of materials created by the medical marketing vendors required extensive use of the wire and mails, including the mailing of invitations to physicians, booking of hotels and airplane tickets, the arrangement of meals, the scheduling of teleconference calls, and the coordination of the content of the presentations on Depakote to be presented at the event. Further instances of the use of mails and wire are contained in the allegations set forth above and incorporated by reference herein.

234. As detailed above, Abbott's pattern of racketeering activity also includes acts indictable under state bribery statutes and 18 U.S.C. § 1952 (use of interstate facilities to conduct unlawful activity). Abbott's acts consisted of, among other things: (a) paying substantial fees and extensive travel benefits to physician participants for agreeing to become CENE faculty; (b) paying physicians to present power points created by the CENE Enterprise; and (c) making outright payments, in the form of grants, to reward doctors who actively prescribed Depakote or promoted it for off-label uses through the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise.

235. The CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise also used interstate facilities, including the mails and wire, to violate state bribery statutes. For example, the unlawful payments to physicians necessarily involved use of mails and/or wire.

236. The conduct of the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1).

237. Abbott's decision for the CENE Enterprise, the PharmaCare Enterprise, and the ABcomm Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

238. The above-described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs and the other Class members. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and the other Class members. Abbott's racketeering activities are part of their ongoing business and constitute a continuing threat to the property of Plaintiffs and the other Class members.

239. Plaintiffs and the other Class members have been injured in their property by reason of these violations in that Plaintiffs and the other Class members have made at least hundreds of millions of dollars in payments for Depakote that they would not have made had Abbott not engaged in its pattern of racketeering activity.

240. Plaintiffs' and the other Class members' injuries were directly and proximately caused by Abbott's racketeering activity as described above.

241. By virtue of these violations of 18 U.S.C. § 1962(c), Abbott is liable to Plaintiffs and the other Class members for three times the damages Plaintiffs and the other Class members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

242. AbbVie, to the extent it has assumed all or part of Abbott's historical liability, is liable to Plaintiffs and the other Class Members as a successor in interest to Abbott, in the same

manner and to the same extent as Abbott.

Second Claim For Relief
Violation of 18 U.S.C. 1962(d)
by Conspiring to Violate 18 U.S.C. 1962(c)
(Brought on Behalf of the Nationwide Class)

243. Plaintiffs incorporate by reference each of the above paragraphs of this Complaint as though fully stated herein.

244. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section."

245. Abbott has violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the § 1962(c) Enterprises described previously through a pattern of racketeering activity.

246. As demonstrated in detail above, Abbott's co-conspirators have engaged in numerous overt and predicate racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs and the other Class members of money.

247. The nature of the above-described Abbott's co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

248. As a direct and proximate result of Abbott's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c),

Plaintiffs and the other Class members have been and are continuing to be injured in their business or property as set forth more fully above.

249. Abbott has sought to and has engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud violations of 18 U.S.C. §§1343 and 1346;

d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952;

250. Abbott's violations of the above federal and state laws and the effects thereof detailed above are continuing and will continue. Plaintiffs and the other Class members have been injured in their property by reason of these violations in that Plaintiffs and the other Class members have made at least hundreds of millions of dollars in payments for Depakote that they would not have made had Abbott not conspired to violate 18 U.S.C. § 1962(e).

251. Plaintiffs' and the other Class members' injuries were directly and proximately caused by Abbott's racketeering activity as described above.

252. By virtue of these violations of 18 U.S.C. § 1962(d), Abbott is liable to Plaintiffs and the other Class members for three times the damages Plaintiffs and the other Class members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

253. AbbVie, to the extent it has assumed all or part of Abbott's historical liability, is liable to Plaintiffs and the other Class Members as a successor in interest to Abbott, in the same manner and to the same extent as Abbott.

Third Claim For Relief
Violation of Illinois Consumer Fraud and
Deceptive Business Practices Act, 815 ILCS 505/2
(Brought on behalf of the Illinois State Subclass)

254. Plaintiff UFCW incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

255. Plaintiff UFCW brings this claim individually and on behalf of the other members of the Illinois State Subclass.

256. At all times material hereto, there has been in effect in the State of Illinois a certain statute known as the Illinois Consumer Fraud and Deceptive Business Practices Act, set forth as Chapter 815, Act 505/2 of the Illinois Compiled Statutes ("ILCS"), which provides in pertinent part, as follows:

> Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby.

257. Plaintiff UFCW and the other members of the Illinois State Subclass paid for purchases of the prescription drug Depakote on behalf of members and beneficiaries who used Depakote for personal, family, or household purposes.

258. Abbott had a statutory duty under 815 ILCS 505/2 to refrain from unfair and deceptive acts or practices in the promotion and sale of Depakote to Plaintiff UFCW and the other members of the Illinois State Subclass.

259. Abbott violated 815 ILCS 505/2 by misrepresenting the characteristics, uses, benefits, quality, and intended purposes of Depakote.

260. Plaintiff UFCW and the other members of the Illinois State Subclass were directly and proximately injured by Abbott's conduct and would not have paid for Depakote had Abbott not engaged in deceptive marketing practices.

261. Abbott engaged in wrongful conduct while, at the same time obtaining, under false pretenses, a significant sum of money from Plaintiff UFCW and the other members of the Illinois State Subclass. Plaintiffs and the other Illinois Subclass members have suffered injury in fact and actual damages including lost money and property as a result of Abbott' violations of 815 ILCS 505/2.

262. Plaintiffs' and the other Illinois Subclass members' injuries were proximately caused by Abbott's fraudulent and deceptive behavior, which was conducted with reckless indifference toward the rights of others, such that an award of punitive damages is appropriate.

263. Pursuant to 815 ILCS 505/7 and 10a, UFCW, on their own behalf and on behalf of the other members of the Illinois Subclass, seek judgment in their favor and against Abbott requiring Abbott to pay monetary and punitive damages for the conduct described herein and pay Plaintiffs' reasonable attorneys' fees and costs of suit.

Fourth Claim For Relief
Violation of New York's Gen. Bus. Law § 349
(Brought on Behalf of the New York Subclass Class)

264. Plaintiff Hillman incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

265. Plaintiff Hillman brings this claim individually and on behalf of the other members of the New York State Subclass.

266. At all times material hereto, there has been in effect in the State of New York a certain statute known as the New York State General Business Law, Section 349, which provides in pertinent part, as follows:

> (a) Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful.

267. Plaintiff Hillman and the other members of the New York State Subclass paid for purchases of the prescription drug Depakote on behalf of members and beneficiaries who used Depakote for personal, family, or household purposes.

268. Abbott had a statutory duty to refrain from unfair and deceptive acts or practices in the promotion and sale of Depakote to Plaintiff Hillman and the other members of the New York State Subclass.

269. Abbott violated this duty by misrepresenting the characteristics, uses, benefits, quality, and intended purposes of Depakote.

270. Plaintiff Hillman and the other members of the New York State Subclass were directly and proximately injured by Abbott's conduct and would not have paid for Depakote had Abbott not engaged in deceptive marketing practices.

271. Abbott's deceptive representations and material omissions to Plaintiff Hillman and the other members of the New York State Subclass are unfair and deceptive acts and practices.

272. Abbott engaged in wrongful conduct while, at the same time obtaining, under false pretenses, a significant sum of money from Plaintiff Hillman and the other members of the New York State Subclass.

273. Plaintiff Hillman and the other members of the New York State Subclass were deceived by Abbott's misrepresentations and omissions.

274. Abbott engaged in wrongful conduct while, at the same time obtaining, under false pretenses, a significant sum of money from Plaintiff Hillman and the other members of the New York State Subclass. Plaintiffs and the other New York State Subclass members have suffered injury in fact and actual damages including lost money and property as a result of Abbott' violations of New York's Gen. Bus. Law § 349.

275. Plaintiffs' and the other New York State Subclass members' injuries were proximately caused by Abbott's fraudulent and deceptive behavior, which was conducted with reckless indifference toward the rights of others, such that an award of punitive damages is appropriate.

276. Pursuant to New York's Gen. Bus. Law § 349(h), Hillman, on their own behalf and on behalf of the other members of the New York State Subclass, seek judgment in their favor and against Abbott requiring Abbott to pay monetary and punitive damages for the conduct described herein and pay Plaintiffs' reasonable attorneys' fees and costs of suit.

Fifth Claim For Relief
Unjust Enrichment
(Brought on Behalf of the Illinois State Subclass Class)

277. Plaintiff UFCW incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

278. Plaintiff UFCW brings this claim for relief on behalf of the Illinois State Subclass.

279. As the intended and expected result of their conscious wrongdoing as set forth in this Complaint, Abbott has profited and benefited from payments Plaintiff UFCW and the other members of the Illinois State Subclass made for Depakote.

280. In exchange for the payments they made for Depakote, and at the time they made these payments, Plaintiff UFCW and the Illinois State Subclass expected that the drug was a safe

and medically effective treatment for the condition, illness, disease, disorder, or symptom for which it was prescribed.

281. Abbott accepted and retained the non-gratuitous benefits conferred by Plaintiff UFCW and the other Illinois State Sublass members, who had they had knowledge of the ineffectiveness of Depakote for the off-label uses it was prescribed and/or the drug's dangerous side effects, would have not purchased the drug.

282. Plaintiff UCFW and the Illinois State Subclass are entitled in equity to seek restitution of Abbott's wrongful profits, revenues and benefits to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Abbott's unjust enrichment.

283. It would be inequitable and unjust for Abbott to retain these wrongfully obtained monies.

284. Accordingly, Plaintiff UCFW and the Illinois State Subclass members seek full restitution of Abbott's enrichment, benefits, and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

285. AbbVie, to the extent it has assumed all or part of Abbott's historical liability, is liable to Plaintiff UCFW and the other the Illinois State Subclass members as a successor in interest to Abbott, in the same manner and to the same extent as Abbott.

Sixth Claim For Relief
Unjust Enrichment
(Brought on behalf of the New York State Subclass)

286. Plaintiff Hillman incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

287. Plaintiff Hillman brings this claim for relief on behalf of the New York State Subclass.

288. As the intended and expected result of their conscious wrongdoing as set forth in this Complaint, Abbott has profited and benefited from payments Plaintiff Hillman and the other members of the New York State Subclass made for Depakote.

289. In exchange for the payments they made for Depakote, and at the time they made these payments, Plaintiff Hillman and the New York State Subclass expected that the drug was a safe and medically effective treatment for the condition, illness, disease, disorder, or symptom for which it was prescribed.

290. Abbott accepted and retained the non-gratuitous benefits conferred by Plaintiff Hillman and the other New York State Subclass members, who had they had knowledge of the ineffectiveness of Depakote for the off-label uses it was prescribed and/or the drug's dangerous side effects, would have not purchased the drug.

291. Plaintiff Hillman and the New York State Subclass members are entitled in equity to seek restitution of Abbott's wrongful profits, revenues and benefits to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Abbott's unjust enrichment.

292. It would be inequitable and unjust for Abbott to retain these wrongfully obtained monies.

293. Accordingly, Plaintiff Hillman and the New York State Subclass members seek full restitution of Abbott's enrichment, benefits, and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

294. AbbVie, to the extent it has assumed all or part of Abbott's historical liability, is liable to Plaintiff Hillman and the other New York State Subcalss Members as a successor in interest to Abbott, in the same manner and to the same extent as Abbott.

Seventh Claim For Relief
Unjust Enrichment
(Brought on Behalf of the Massachusetts State Subclass)

295. Plaintiff Local 404 incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

296. Plaintiff Local 404 brings this claim for relief on behalf of the Massachusetts State Subclass.

297. As the intended and expected result of their conscious wrongdoing as set forth in this Complaint, Abbott has profited and benefited from payments Plaintiff Local 404 and the other members of the Massachusetts State Subclass made for Depakote.

298. In exchange for the payments they made for Depakote, and at the time they made these payments, Plaintiff Local 404 and the Massachusetts State Subclass expected that the drug was a safe and medically effective treatment for the condition, illness, disease, disorder, or symptom for which it was prescribed.

299. Abbott accepted and retained the non-gratuitous benefits conferred by Plaintiff Local 404 and the other Massachusetts State Subclass, who had they had knowledge of the ineffectiveness of Depakote for the off-label uses it was prescribed and/or the drug's dangerous side effects, would have not purchased the drug.

300. Plaintiff Local 404 and the Massachusetts State Subclass are entitled in equity to seek restitution of Abbott's wrongful profits, revenues and benefits to the extent, and in the

amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Abbott's unjust enrichment.

301. It would be inequitable and unjust for Abbott to retain these wrongfully obtained monies.

302. Accordingly, Plaintiff Local 404 and the Massachusetts State Subclass members seek full restitution of Abbott's enrichment, benefits, and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

303. AbbVie, to the extent it has assumed all or part of Abbott's historical liability, is liable to Plaintiff Local 404 and the other Massachusetts State Subclass as a successor in interest to Abbott, in the same manner and to the same extent as Abbott.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the other Class and Subclass members, respectfully request that the Court grant judgment in their favor and against Defendants for each claim for relief, jointly and severally, as follows:

a. On Plaintiffs' RICO claims, three times the damages Plaintiffs and the other Class and Subclass members have sustained as a result of Defendants' conduct alleged herein, such amount to be determined at trial;

b. On Plaintiffs' and Subclass members' 815 ILCS 505/2 and New York's Gen. Bus. Law § 349 claims, restitution, disgorgement, and/or such orders or judgments as may be necessary to restore to any Subclass member as a result of the unlawful and/or wrongful conduct alleged herein;

c. Awarding Plaintiffs and the other Class and Subclass members other appropriate equitable relief, including restitution of Defendants' ill-gotten

gains acquired as a result of the unlawful and/or wrongful conduct alleged herein;

d. Awarding Plaintiffs their costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

e. Awarding Plaintiffs and the other Class and Subclass members such other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury on all claims so triable.

Dated: August 16, 2013

GRANT & EISENHOFER P.A.

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